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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,171	11/01/2006	Taeko Iino	47234-5002-00-US (219084)	1995
55694 7590 09/04/2008 DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209			EXAMINER HENRY, MICHAEL C	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 09/04/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,171	<b>Applicant(s)</b> IINO ET AL.	
	<b>Examiner</b> MICHAEL C. HENRY	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13, 16-24, 37, 38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13, 16-24, 37 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/16/05 &amp; 02/12/08</u> .                                 | 6) <input type="checkbox"/> Other: ____.                          |

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### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/02/08 has been entered.

The following office action is a responsive to the Amendment filed, 05/02/08.

The amendment filed 05/02/08 affects the application, 10/561,171 as follows:

1. Claims 13 and 16 have been amended. Claims 25 and 26 have been canceled. New Claims 37 and 38 have been added. Applicants' amendments have overcome the claims objections made in the prior office action. Consequently, the claims objections are withdrawn. However, the rejections under made under 35 U.S.C. 103(a) are maintained.
2. The responsive to applicants' arguments is contained herein below.
3. Claims 13, 16-24, 37, 38 are pending in the application.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 16-24, 37, 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 13 and 16 recite the phrases “reducing muscular fatigue” and “within one hour before and after physical exercise”. However, the claims are indefinite since it is unclear whether or not in order to practice applicants’ invention, it is necessary for the human being that is treated to exercise, and whether or not the claimed invention can only be practiced on said human being that exercises. Furthermore, the claim is also indefinite since it is unclear whether or not the muscular fatigue that is been treated or reduced is limited to muscular fatigue that is a result of exercising especially since administration of the proanthocyanin is “within one hour before and after physical exercise”.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13, 16-24, 37, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (US 6,372,266).

In claim 13, applicant claims a method for reducing muscular fatigue, comprising administering proanthocyanidin a human being in an amount effective to reduce muscular fatigue within one hour before and after physical exercise. Claim 16 is drawn to a method for reducing fatigue comprising administering a health food containing proanthocyanidin as an effective ingredient to a human being within one hour before and after physical exercise. Claims 17-24 are drawn to said method wherein the health food is in specific forms including solid food,

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beverage, tablet and wherein the proanthocyanidin is an extract derived from pine bark or is an oligomeric proanthocyanidin.

Suzuki et al. disclose that a composition comprising a pine bark extract and containing proanthocyanidins as an effective component thereof can be administered to humans to treat leg cramps (i.e., sudden, involuntary, spasmodic muscular contraction causing severe pain) and chronic fatigue syndrome (CFS) (see col. 2, line 20 to col. 3, line 8). Furthermore, Suzuki et al. disclose that the composition is widely used as a nutritional supplement food (see col. 2, lines 20-26). Furthermore, Suzuki et al. disclose that pine bark extract and containing proanthocyanidins can be in the form of tablets, liquid and powdery preparations (see col. 2, lines 1-11; col. 4, lines 35-40 and abstract). Suzuki et al. disclose a method for treating dysmenorrhea (which is the occurrence of painful cramps which are sudden, involuntary, spasmodic muscular contractions causing severe pain) during menstruation, characterized in that proanthocyanidin is administered to a human (see abstract). It should also be noted that muscular fatigue and myalgia (muscle pain) are associated with Chronic Fatigue Syndrome (CFS) (see Exhibit A attached, <http://www.immunesupport.com/chronic-fatigue-syndrome-causes.htm>). Also, it should be noted that Chronic fatigue and immune dysfunction syndrome (abbreviated CFIDS or CFS) is a group of symptoms associated with severe, almost unrelenting fatigue. It should be noted that it is known that muscular cramps (e.g., a leg cramp) are associated with muscular fatigue and shortened muscle contraction (see e.g. Exhibits B as attached).

The difference between applicant's claimed method and the method of Suzuki et al. is that Suzuki et al. do not exemplify the treatment or reduction of muscular fatigue by

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administering the composition to said human. However, Suzuki et al. disclose that Chronic fatigue syndrome and leg cramps can be treated by administering their composition containing proanthocyanidin to a human being and consequently a skilled artisan would be motivated to treat fatigue such as muscular fatigue in said human since Suzuki et al. disclose that Chronic fatigue syndrome can be treated and especially since it is known that muscular fatigue is associated with Chronic Fatigue Syndrome (CFS). Also, the fact that it is known that muscular cramps (e.g., a leg cramp) are associated with muscular fatigue and shortened muscle contraction provides even greater motivation to a skilled artisan to treat muscular fatigue in said human with said proanthocyanidin composition.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to treat or reduce muscular fatigue by administering Suzuki et al.'s composition containing proanthocyanidin to a human, since Suzuki et al. disclose that pine bark extract containing proanthocyanidins as an effective component can be administered to a humans to treat chronic fatigue syndrome and leg cramps and especially since it is known that muscular fatigue is associated with Chronic Fatigue Syndrome (CFS) and muscular cramps (e.g., a leg cramp) are associated with muscular fatigue.

One having ordinary skill in the art would have been motivated, to treat or reduce muscular fatigue by administering Suzuki et al.'s composition containing proanthocyanidin to a human, since Suzuki et al. disclose that pine bark extract containing proanthocyanidins as an effective component can be administered to a humans to treat chronic fatigue syndrome and leg cramps and especially since it is known that muscular fatigue is associated with Chronic Fatigue Syndrome (CFS) and muscular cramps (e.g., a leg cramp) are associated with muscular fatigue.

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It should be noted that the use of specific formulations and amounts or quantities of proanthocyanidin is well within the purview of a skilled artisan and depends on factors such as the type and/or severity of the condition treated and the age, weight and type of individual treated.

### ***Response to Arguments***

Applicant's arguments with respect to claims 13, 16-24, 37, 38 have been considered but are not found convincing.

The applicant argues that Suzuki teaches the use of French maritime pine bark extract containing proanthocyanidins, also known as Pycnogenol, for treating dysmenorrhea<sup>2</sup> and endometriosis.<sup>3</sup> Suzuki, col. 4, lines 18-20 and 25. Suzuki suggests administering Pycnogenol over 14 days from 7 days prior to menstruation, over an entire month, or once a dose of 60 mg. Suzuki, col. 5, lines 2-8. Suzuki does not teach or suggest a method for reducing muscular fatigue, comprising administering proanthocyanidin to a human being in an amount effective to reduce muscular fatigue within one hour before and after physical exercise, as presently claimed. However, although applicant administer Pycnogenol over 14 days from 7 days prior to menstruation, applicant also administer the Pycnogenol continuously for a month and also once. This suggests that the Pycnogenol can be administered at any time (continuously) regardless of the presence or absence exercise and especially since the average menstrual cycles length is 28 days. Moreover, as set forth above, it should be noted that Suzuki et al. disclose that a composition comprising a pine bark extract and containing proanthocyanidins as an effective component thereof can be administered to a humans to treat leg cramps (i.e., sudden, involuntary, spasmodic muscular contraction causing severe pain) and chronic fatigue syndrome

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(CFS) (see col. 2, line 20 to col. 3, line 8). Furthermore, Suzuki et al. disclose that the composition is widely used as a nutritional supplement food (see col. 2, lines 20-26). Furthermore, Suzuki et al. disclose that pine bark extract and containing proanthocyanidins can be in the form of tablets, liquid and powdery preparations (see col. 2, lines 1-11; col. 4, lines 35-40 and abstract). Suzuki et al. disclose a method for treating dysmenorrhea (which is the occurrence of painful cramps which are sudden, involuntary, spasmodic muscular contractions causing severe pain) during menstruation, characterized in that proanthocyanidin is administered to a human (see abstract). It should also be noted that muscular fatigue and myalgia (muscle pain) are associated with Chronic Fatigue Syndrome (CFS) (see Exhibit A attached, <http://www.immunesupport.com/chronic-fatigue-syndrome-causes.htm>). Also, it should be noted that Chronic fatigue and immune dysfunction syndrome (abbreviated CFIDS or CFS) is a group of symptoms associated with severe, almost unrelenting fatigue. It should be noted that it is known that muscular cramps (e.g., a leg cramp) are associated with muscular fatigue and shortened muscle contraction (see e.g. Exhibits B as attached).

The applicant argues that the Office refers to Maquirriain *et al.*, "The Athlete With Muscular Cramps: Clinical Approach," *J. Am. Acad. Orthop. Surg.* 15:425-31 (July 2007) ("Maquirriain") for the proposition that "muscular cramps (e.g., a leg cramp) are associated with muscular fatigue." Office Action, pages 3-4. Maquirriain in fact discloses that leg cramps may be "associated" with a wide variety of chronic conditions unrelated to muscle fatigue, e.g., radiculopathies, Parkinson's disease, hypothyroidism, diabetes mellitus, vascular problems, electrolyte disorders, and metabolic myopathies. Moreover, Maquirriain (Exhibit B) was used



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relate the fact that it is known that muscular cramps (e.g., a leg cramp) are associated with muscular fatigue and shortened muscle contraction (see e.g. Exhibits B).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry  
August 31, 2008.

/Shaojia Anna Jiang, Ph.D./  
Supervisory Patent Examiner  
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